Lateral Extra-Articular Tenodesis combined with anterior cruciate ligament reconstruction is effective in knees with additional features of lateral, hyperextension or increased rotational laxity: a matched cohort study

Running title: Outcomes of ACLR with Lateral tenodesis

Ahmed Mahmoud, MD, MS, Stephen Torbey, MBBS, Conor Honeywill, B.Phty, Peter Myers, F.R.A.C.S

1. School of Medicine, Griffith University, Parkland Drive, Gold Coast, QLD 4222 Australia

2. Brisbane Orthopaedic & Sports Medicine Centre, The Brisbane Private Hospital, Wickham Terrace, Brisbane, QLD 4000, Australia.

Corresponding author: Dr Ahmed Mahmoud, Brisbane Private hospital
a.mahmoud@uq.edu.au Telephone: (07) 3832 2181 Fax: (07) 3834 6637
Lateral Extra-Articular Tenodesis combined with anterior cruciate ligament reconstruction is effective in knees with additional features of lateral, hyperextension or increased rotational laxity: a matched cohort study

Abstract

Purpose: To investigate the patient reported outcome measures (PROMs) and graft survival of combined anterior cruciate ligament reconstruction and lateral extra-articular tenodesis (ACLR-LET) compared with a matched cohort having ACLR alone.

Methods: Patients were retrospectively recruited from a consecutive series of primary ACLR-LET, between 1996-2015, with a minimum post-surgical time of four years. ACLR-LET were matched with isolated ACLR for age, gender and operation year. The indications for adding LET were lateral laxity of grade 1 or 2, hyperextension laxity and/or increased rotational laxity of 5 – 10°. The technique used involved detaching a strip of ilio-tibial band proximally, before being passed deep to the lateral collateral ligament, looped through Kaplan’s fibres and sutured back onto itself at physiological tension. PROMs used were the Lysholm Knee Scoring Scale (LKS), Tegner Activity Scale (TAS), Oxford Knee Score (OKS) and International Knee Documentation Committee (IKDC) subjective knee form. Failure was defined as graft rupture. Student’s t-test was used to compare the matched groups and Kaplan Meier analysis for survivorship.

Results: 83 patients had ACLR-LET between 1996-2015. 9 revision cases and 2 with less than 4 years follow-up were excluded. The remaining 72 ACLR-LET patients were matched and included in the survival analysis. 70% of patients completed the PROMs. In both groups, 76% were males and the mean age was 25 years (standard deviation ± 8.5). The median follow-up was 10 years (Interquartile range 6.7 years). There was no significant change of PROMs.
(LKS: \( P=0.82 \), 95\% CI -13 to 11; IKDC: \( P=0.07 \), CI -1 to 24; OKS: \( P=0.5 \), CI -8 to 4; TAS: \( P=0.5 \), CI -1 to 23) between the groups. The pre-operative to post-operative PROMs, except the TAS, improved significantly, clinically and statistically. There was no statistically significant difference in graft failure between the ACLR-LET group (n=4, 5\%) and the ACLR group (n=9, 11\%) (log-rank \( P=0.099 \)).

**Conclusion:** ACLR-LET shows good graft survival and PROMs in a high-risk population. This suggests that LET is an effective technique to restore joint stability to a knee with additional features of laxity.

**Level of Evidence:** III Matched Cohort study

**Introduction:**

The management of anterior cruciate ligament (ACL) injury in patients at a higher risk of re-rupture remains controversial. It has been shown that risk factors for graft rupture include younger age (<20 years old), those with generalised hypermobility and physiologic knee hyperextension, \(^1\) and those returning to high risk (pivoting) sports.\(^2\) Further, Saita et al demonstrated that knee hyperextension and a small lateral condyle is associated with greater anterolateral rotatory instability.\(^3\) Standard intra-articular ACL reconstruction (ACLR) techniques reduce anterior tibial translation but does not satisfactorily address anterolateral rotatory instability.\(^4\) Therefore, ACLR is often combined with extra-articular reconstruction (ACLR-LET) to reinforce the knee joint.

Rotatory instability is difficult to manage in patients who continue to demonstrate a positive pivot shift after isolated ACLR. Several extraarticular procedures have been proposed to resolve rotatory instability. The Mcintosh, Lemaire and ALL reconstruction techniques have been discussed in the literature.\(^5\)\(^-\)\(^8\) The ALL reconstruction was found to reduce the graft failure rate in large series of patients at two years follow up.\(^9\) The modified Lemaire
Technique has been shown to have low complication rate and reduction in pivot shift test.\textsuperscript{6} The main concern relating to lateral extraarticular techniques is over constraint of the lateral compartment and early osteoarthritis. However, Ferretti et al. 2016 showed that the modified MacIntosh technique did not lead to increased incidence of osteoarthritis.\textsuperscript{10} The research into extraarticular techniques remains highly variable and there is limited long-term follow up.\textsuperscript{11}

The purpose of this is to investigate the patient reported outcome measures (PROMs) and graft survival of combined anterior cruciate ligament reconstruction and lateral tenodesis compared with a matched cohort having ACLR alone. The primary outcome is the PROMs. We hypothesise that the PROMs will be equivalent in the two groups and graft failure rate will be lower in the ACLR-LET group.

\textbf{Methods:}

This is a retrospective case-control study of patients recruited from a single surgeon series of ACLR from 1996 to 2015. The inclusion criteria were a primary semitendinosus-gracilis (St-G) ACLR-LET with a minimum post-operative time of 4 years. Primary ACLR-LET represented only 3\% of the 2607 ACLR carried out by the senior author. Other ACLR-LETs were completed by the senior author, however these were for revision ACLR. LET was reserved to patients with predisposing factors for increased graft failure. Patients were excluded if they failed to consent to data collection for research purposes, had a concomitant osteotomy or had a revision ACLR. Also, a matched cohort of isolated ACLR was recruited to compare PROMs and ACL graft survivorship. The patients were matched for age (within 3 years), gender and year of operation (within a year).
Following cohort selection, patients were contacted firstly by email to be invited to participate within the study with an information sheet and consent form attached. If consented, patients were subsequently sent a secure link to an online survey looking at the outcomes below. If there was no response to email, a research investigator would call to discuss further. The individual surgeon was not responsible for contacting patients, in order to reduce bias. Ethical approval to contact patients for long term follow-up beyond standard consultations was gained from the Hospital Human Research Ethics board.

**Surgical indication and technique:**

The ACLR and ACLR-LET groups had an arthroscopically assisted anatomic quadrupled autologous St-G graft. The indications for adding LET to ACLR were lateral laxity of grade 1 or 2, hyperextension laxity and/or increased rotational laxity of 5 – 10° measured pre-operatively in clinic. The LET is performed after the completion of the ACLR. The surgical approach is made through a curved lateral incision centred over the lateral epicondyle of the femur. A 12-15 cm strip of ilio-tibial band (ITB) is detached proximally, not including the posterior curved fibres (Figure 1). Through the defect in the ITB a triangular area of fat is identified. Dissection through this identifies the distal fibres of the lateral intermuscular septum known as Kaplan’s fibres. These can be easily palpated and then exposed. The strip of ITB is passed deep to the lateral collateral ligament. It is then passed through the lateral distal intermuscular septum from posterior to anterior and adjacent to the femur. This is sutured to itself at physiological tension with the foot in neutral rotation and the knee at around 50° flexion. The ITB is closed from proximal to as far distally as possible and the wound is then closed. The rehabilitation protocol was unchanged from the standard ACLR protocol.
Outcome Measures:

The demographics and peri-operative data were collected from the patients’ medical charts. The PROMs were the primary outcome measure. PROMs were completed during pre-operative assessment and the latest follow up. The PROMs collected were the Lysholm Knee Scoring Scale (LKS), Tegner Activity Scale (TAS), Oxford Knee Score (OKS) and International Knee Documentation Committee (IKDC) subjective knee form. The patients were asked their level of satisfaction with the procedure. Also, the patients were contacted and the medical charts were reviewed to record ACL graft failure and post-operative complications. Graft failure was defined as graft rupture proven on magnetic resonance imaging.

Statistical Analysis:

The program SPSS Statistics v25 (SPSS Inc. Illinois, USA) was used for statistical analysis. The primary outcome measure was the LKS and power analysis was performed to determine the number of patients required to detect a clinical minimal detectable change of 10 points with an estimated standard deviation of 10.\textsuperscript{12,13} 17 subjects are needed in each group to achieve a power of 0.8, however, the aim is to recruit all patients during the time period. The minimal clinically important difference (MCID) was calculated using the distribution-based method as half the standard deviation of the preoperative measure.\textsuperscript{14} A Student’s \textit{t}-test was used to assess whether the change in PROMs is different between the ACLR-LET and ACLR. A paired \textit{t}-test was used to determine the difference in PROMs between pre-operative and latest follow-up scores for each group. The analysis of demographic was performed using the Mann-Whitney U test for data that was not normally distributed and \chi\textsuperscript{2}-square test for categorical variables. As patients were matched for age, gender, operative year and side, statistical analysis was not performed for these variables. Kaplan-Meier survivorship analysis
was used to estimate survivorship. Graft failure was used as the endpoint. A $P$ value of less than .05 were considered statistically significant.

**Results:**

83 patients had ACLR-LET between 1996 and 2015, however, 9 were revision cases and 2 had follow-up less than 4 years, therefore were excluded (Figure 2). 72 patients with ACLR-LET were included in the study and were matched to the same number of ACLR without LET. 43% (n=31) of patients in the ACLR-LET had rotational laxity and 65% (n=47) had lateral laxity. The patients’ demographics are demonstrated in table 1. The median follow-up was 10 years in both groups with an interquartile range of 6.7 years. The only significant difference in demographics was that the ACLR-LET had a longer median time from injury to surgery.

30% (n=22) of patients in the ACLR-LET and 29% (n=21) in the ACLR groups did not complete the pre-operative PROMs. The Shapiro-Wilk test demonstrated that the data is normality distributed. The student’s t-test demonstrated that the change in PROMs is not significantly different between the two groups (Table 2). PROMs significantly improved between pre- and post-operative follow-up in all outcomes except the TAS (Table 2). The pre-operatively TAS score had a mean of 5 (Standard deviation 2.6 in ACLR-LET, 2.8 in ACLR) in both groups which indicates a high level of baseline activity of the subjects. Over 85% of patients were either satisfied or very satisfied with the procedure in both groups.

The MCID was calculated using the distribution-based methods. The MCID was 9.1 for LKS, 8.8 for IKDC, 5.2 for OKS and TAS was 1.25. In the ACLR-LET group, the PROMs improved above the MCID in 96% for LKS, 88% for IKDC 84% for OKS and 36% for TAS. In the ACLR group, the PROMs improved above the MCID in 86% for LKS, 100% for IKDC 67% for OKS and 47% for TAS. Also, the lower limit of the confidence intervals (table 2) was higher than the
MCID for the LKS and IKDC. The lower limit of the OKS was only 0.2 points below the MCID and the TAS’s MCID was within the confidence interval.

The graft failure rate was 5% (n=4) in the ACLR-LET group and 11% (n=9) in the ACLR group (Figure 3). However, this was not significantly different on the log-rank test (p-value=.099) as the study was not sufficiently powered for detecting graft failure difference. The complications rate in the two groups was low. In the ACLR-LET group, three patients had meniscus tears requiring a subsequent arthroscopy. There were no complications related to the lateral tenodesis incision. In the ACLR group, one patient developed a DVT, one patient had a superficial wound infection and four patients had a subsequent meniscus tear requiring arthroscopy.

Discussion:

The principle finding of this study is that primary ACLR-LET was associated with equivalent improvement of PROMs and rates of graft failure in comparison to ACLR alone. This is despite the fact that the patients receiving the ACLR-LET had lateral laxity, hyperextension laxity and/or increased rotational laxity which are factors well known to increase the risk of graft failure. In both groups the PROMs, improved significantly from the pre to post-operative follow-up. Patients were able to return to their pre-injury level of activity according to the TAS. The improvement in PROMs was above the calculated MCID for LKS, IKDC and OKS. The result proves yet again the effectiveness of ACLR with or without LET in improving patients’ outcomes and quality of life. The study was not adequately power to detect a different in graft failure, therefore, did not reach statistical significance. However, the graft failure was 6% in the ACLR-LET despite a biased selection of higher risk patients into the group is clinically relevant to practice. It indicates that LET is a safe and effective addition to ACLR with a low failure rate of the ACL graft.
The addition of LET to ACLR has been previously proposed using several different techniques and indications. Noyes et al. found the addition of extra articular procedure to ACLR using allograft reduced failure rate in chronic ACLR laxity. However, Noyes’ indication for LET was chronic laxity, while most of our patients had ACLR with six months of injury. Ferretti et al. found ACLR-LT had fewer arthritic changes and reduced failure rate, in a retrospective series of patients with a minimum follow up of 10 years. Several reviews have been published recently on whether the addition of a lateral extra-articular tenodesis improves outcomes. Song et al. and Hewison et al. both reported that LET statistically improved pivot-shift test when compared to an isolated ACLR. Additionally, two studies reported decreased lateral translation on radiological stress testing. However, a systematic review and meta-analysis conducted by Devitt et al reported no difference when LET is added to ACLR in functional, subjective or clinical outcomes compared to isolated ACLR. The limitations of these reviews were that, except for one, they focused on short-term outcomes. When considering graft failure or re-rupture rate, a recent literature review commented that the combination of a LET to a standard intra-articular ACLR results in decreased failure rates compared to the traditional intra-articular technique alone. Importantly, this review identified that a number of these studies are underpowered and there is a large variety in the techniques utilised for extra-articular tenodesis. More recently, the STABILITY study found a reduced rate of clinical failure and graft rupture in patient undergoing ACLR-LET compared to ACLR alone. Similarly to our study, the graft rupture rate in the ACLR-LET was 4% and 11% in the ACLR. It was the first randomised control trial with adequate power to detect a different in failure rate. However, the STABILITY trial found 3% of patient require hardware removal as a staple fixation was used, while our technique offers the advantage of soft tissue fixation alone.
In this study, patients selected for a LET were those who had some degree of increased laxity and were at a higher risk of a recurrent ACL injury. Our indications for LET initially were limited to revisions and lateral laxity before postero-lateral reconstructions were popular. The indications have expanded over the years to include hyperextension laxity and more recently generalised ligamentous laxity especially in teenagers. Since the STABILITY study, the indications have increased even more.\textsuperscript{24} The technique used by the senior author has been unchanged over 20 years. It is the senior author’s belief that attaching the strip of ITB to the distal fibres of the intermuscular septum avoids over-constraint of the joint which may occur with techniques involving the use of anchors, staples or bone tunnels.

**Limitations**

There are a number of limitations in this study. Firstly, due to its retrospective nature, the groups were not randomised but rather matched based upon patients demographics. This has resulted in a selection bias, with the ACLR-LET group receiving the additional LET for increased anterolateral rotatory stability. Secondly, the study has a low statistical power for detecting a difference in graft failure rates. Therefore, although the selection bias places favour in the ACLR-LET group as the demographic has higher rates of graft failure, this cannot be determined from this study as adequate powering did not occur. Further investigations are required to determine if there is a significant statistical difference between techniques in graft failure. Lastly, 30% of patients did not complete the PROMs. Despite being of relatively equal loss, there may be a transfer bias with the individuals lost to follow-up not being matched.

**Conclusion**
ACLR-LET shows good graft survival and PROMs in a high-risk population. This suggests that LET is an effective technique to restore joint stability to a knee with additional features of laxity.

References


**Figures legends**
**Figure 1:** Intraoperative illustration of the iliotibial band (black arrow) and Kaplans fibres (grey arrow). The patient is in supine with the knee flexed and the incision is made over the lateral aspect of the knee.

**Figure 2:** A flowchart demonstrating the reasons for exclusion of patients from the study. The included patients had primary anterior cruciate ligament reconstruction with lateral extra-articular tenodesis (ACLR-LET).

**Figure 3:** Kaplan Meier Survival curve with graft failure as the endpoint in patients who underwent Anterior cruciate reconstruction with lateral tenodesis (Grey) verses without (Black)

### Tables

**Table 1: Subject Demographics**

<table>
<thead>
<tr>
<th></th>
<th>ACLR-LET *(N=72)</th>
<th>ACLR Alone *(N=72)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (± years)</td>
<td>25 (±8.5)</td>
<td>25 (±8.4)</td>
<td></td>
</tr>
<tr>
<td>Follow-up (median years)</td>
<td>10 (IQR 6.7)</td>
<td>10 (IQR 6.7)</td>
<td></td>
</tr>
<tr>
<td>Sex (male)</td>
<td>76%</td>
<td>76%</td>
<td></td>
</tr>
<tr>
<td>Knee Side (left)</td>
<td>61%</td>
<td>61%</td>
<td></td>
</tr>
<tr>
<td>Injury to ACLR (median months)</td>
<td>4.9 (IQR 22)</td>
<td>2.8 (IQR 4.9)</td>
<td>.009†</td>
</tr>
<tr>
<td>Lateral collateral ligament injury</td>
<td>65%</td>
<td>12%</td>
<td>&lt;.001‡</td>
</tr>
<tr>
<td>Medial collateral ligament injury</td>
<td>7%</td>
<td>12%</td>
<td>.37‡</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----</td>
<td>-----</td>
<td>------</td>
</tr>
</tbody>
</table>

**Meniscus tears**

<table>
<thead>
<tr>
<th>Medial meniscus</th>
<th>38%</th>
<th>30%</th>
<th>.45 †</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral Meniscus</td>
<td>29%</td>
<td>33%</td>
<td>.64</td>
</tr>
</tbody>
</table>

*ACLR, Anterior cruciate ligament reconstruction; LET, Lateral extra-articular tenodesis

†Mann-Whitney U Test ‡chi-square test

---

**Table 2: Change in patient reported outcome measures (PROMs) pre- and post-operatively.** The student’s t-test compares the significance of change in PROMs of the two groups

<table>
<thead>
<tr>
<th></th>
<th>Preop</th>
<th>Postop</th>
<th>Paired t-test (P-value, CI) ‡</th>
<th>Student’s t-test P-value &amp; CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LKS†</strong></td>
<td>ACLR-LET*</td>
<td>58.1±16.1</td>
<td>84.2±15.1</td>
<td>26 (&lt;.001, 17 to 35)</td>
</tr>
<tr>
<td></td>
<td>ACLR*</td>
<td>67±16.6</td>
<td>91.3±10.7</td>
<td>24 (&lt;.001, 15 to 33)</td>
</tr>
<tr>
<td><strong>IKDC</strong></td>
<td>ACLR-LET*</td>
<td>46.6±14</td>
<td>78±18</td>
<td>31 (&lt;.001, 22 to 40)</td>
</tr>
<tr>
<td></td>
<td>ACLR*</td>
<td>53.6±17</td>
<td>96±7.5</td>
<td>42 (&lt;.001, 34 to 51)</td>
</tr>
<tr>
<td><strong>OKS</strong></td>
<td>ACLR-LET*</td>
<td>35±8.6</td>
<td>43.7±5</td>
<td>9 (&lt;.001, 5 to 12)</td>
</tr>
<tr>
<td></td>
<td>ACLR*</td>
<td>38±11.6</td>
<td>45±3.8</td>
<td>7 (.025, 5 to 12)</td>
</tr>
<tr>
<td>TAS</td>
<td>ACLR-LET*</td>
<td>5±2.5</td>
<td>5.6±2.3</td>
<td>0.6 (.272, -0.6 to 1.9)</td>
</tr>
<tr>
<td>-----</td>
<td>---------------</td>
<td>-------</td>
<td>---------</td>
<td>-------------------------</td>
</tr>
<tr>
<td></td>
<td>ACLR*</td>
<td>5.3±2.8</td>
<td>6.3±2.6</td>
<td>1 (.163, -0.6 to 3.3)</td>
</tr>
</tbody>
</table>

* ACLR-LET, Anterior cruciate ligament reconstruction with lateral extra-articular tenodesis; ACLR, Anterior cruciate ligament reconstruction

† LKS, Lysholm Knee Score; IKDC, International Knee Documentation Committee; OKS, Oxford Knee Score; TAS, Tegner Activity Scale

† Paired t-test to assess the significance of change of PROMs from pre to post-operative values; CI, 95% Confidence Interval
ACLR 1996 to 2015 (n=2607)

ACLR without LET (n=2524)

ACLR-LET (n=83)

Revision cases (n=9)

Follow less than 4 years (n=2)

ACLR-LET (n=72) included in graft survival analysis

70% with completed PROMs (n=50)